

REMARKS

Rejection of Claims 4, 5, 12 and 13 Under 35 U.S.C. 102(b) Over  
Arriza

Claims 4, 5, 12 and 13 are rejected by the Examiner under 35 U.S.C. 102(b) over the Arriza reference for the reasons set forth on page 5 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The present invention as recited in claim 4, as amended, relates to an amino acid sequence selected from the group consisting of (i) an amino acid sequence coded by an isolated nucleic acid sequence of alternative splice variants selected from the group consisting of:

(a) the nucleic acid sequence depicted in any one of SEQ ID NO: 1 to SEQ ID NO: 26;

(b) nucleic acid sequences having at least 90% identity with the sequence of (a) with the proviso that each sequence is different than the original nucleic acid sequence from which the sequences of (a) have been varied by alternative splicing; and

(c) fragments of (a) or (b) of at least 20 b.p., provided that said fragment contains a sequence which is not present, as a continuous stretch of nucleotides, in the original nucleic acid

sequence from which the sequences of (a) have been varied by alternative splicing; and

(ii) homologues of the amino acid sequences of (i) in which one or more amino acids has been added, deleted, replaced or chemically modified in the region or adjacent to the region where the amino acid sequences differs from the original amino acid sequence, coded by the original nucleic acid sequence from which the variant has been varied.

The Examiner's position is that the instant claims do not clearly exclude the art-known splice form of the polypeptide. That is, the Examiner's position is that the Arriza et al. reference teaches the cDNA encoding the claimed amino acid. Applicants respectfully disagree.

The Arriza et al. reference merely refers to the original sequence. The Arriza et al. reference does not disclose or suggest the claimed splice variants of the invention. Contrary to the position taken by the Examiner, Applicants' invention does not encompass the sequence known in the art. Rather, claims 4, 5, 12 and 13 are directed to the sequences recited in the present application, which are the splice variants.

Furthermore, the subject matter of claim 1 has been incorporated into claim 4 and specifically recites a "nucleic acid sequence of an alternative splicing variant."

Accordingly, in view of the remarks hereinabove, the rejection of claims 4, 5, 12 and 13 under 35 U.S.C. 102(b) over the Arriza reference should be withdrawn by the Examiner.

Rejection of Claims 4, 5, 12 and 13 Under 35 U.S.C. 112, Second Paragraph

Claims 4, 5, 12 and 13 are rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth on pages 6-7 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner's position is that the instant claims do not clearly exclude the art-known splice form of the polypeptide. Applicants respectfully disagree.

The Examiner's attention is directed to page 9, lines 1-2 of the present specification, which defines the original sequence. That is, the original sequence is clearly defined as "the amino acid or nucleic acid sequence from which the variant of the invention have been varied as a result of alternative splicing."

The Examiner's attention is further directed to the Table on page 21 of the present specification. The Examiner will note that the Table shows that the Mineralcorticoid (MCR\_HUMAN) splice variant is expressly defined with reference to the original protein (e.g. "Replacement of 147 C-terminal amino acids, including part of

the steroid binding domain of the **original** protein, by alternative 8 amino acids."

Accordingly, in view of the remarks hereinabove, the rejection of claims 4, 5, 12 and 13 under 35 U.S.C. 112, second paragraph, should be withdrawn by the Examiner.

**Rejection of Claims 4, 5, 12 and 13 Under 35 U.S.C. 101; Rejection of Claims 4, 5, 12 and 13 Under 35 U.S.C. 112, First Paragraph**

Claims 4, 5, 12 and 13 are rejected by the Examiner under 35 U.S.C. 101 for the reasons set forth on pages 2-3 of the Office Action. Claims 4, 5, 12 and 13 are rejected by the Examiner under 35 U.S.C. 112, first paragraph, for the reasons set forth on pages 3-5 of the Office Action. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner concedes that Applicants allege a utility. However, the Examiner disagrees with Applicants' statement of utility on a technical basis (e.g. "the treatment of hypertension within this receptor system would require reduction of said receptor, not an increase..As such, the asserted utility is not credible.")

Applicants respectfully submit that the Examiner has not set forth a *prima facie* case of lack of utility. Applicants have asserted a utility, but the Examiner refuses to accept it. The

Examiner basis the rejection on his personal opinion rather than upon art recognized scientific principles. If the Examiner would like to rely on his personal technical knowledge rather than upon the state of the art, then the Examiner is respectfully requested to submit a Declaration attesting to that "evidence". Otherwise, Applicants statement of utility should and must be accepted. Thus, the rejections under 35 U.S.C. 101 and 112, first paragraph, should be withdrawn by the Examiner as the Examiner has not set forth a *prima facie* case of lack of utility.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$465.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc. S. Weiner (Reg. No. 32,181) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By   
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Attachment(s) :

MARKED-UP VERSION SHOWING THE CHANGES MADE

Claims 4, 5 and 12 are amended as follows:

4. (Amended) An amino acid sequence selected from the group consisting of:

(i) an amino acid sequence coded by [the] an isolated nucleic acid sequence of alternative splice variants [of Claim 1;] selected from the group consisting of:

(a) the nucleic acid sequence depicted in any one of SEQ ID NO: 1 to SEQ ID NO: 26;

(b) nucleic acid sequences having at least 90% identity with the sequence of (a) with the proviso that each sequence is different than the original nucleic acid sequence from which the sequences of (a) have been varied by alternative splicing; and

(c) fragments of (a) or (b) of at least 20 b.p., provided that said fragment contains a sequence which is not present, as a continuous stretch of nucleotides, in the original nucleic acid sequence from which the sequences of (a) have been varied by alternative splicing; and

(ii) homologues of the amino acid sequences of (i) in which one or more amino acids has been added, deleted, replaced or chemically modified in the region or adjacent to the region where the amino acid sequences differs from the original amino

acid sequence, coded by the original nucleic acid sequence from which the variant has been varied.

5. (Amended) An amino acid sequence according to Claim [5] 4, as depicted in any one of SEQ ID NO: 27 to SEQ ID NO: 52.

12. (Amended) A pharmaceutical composition comprising a pharmaceutically acceptable carrier and as an active ingredient an agent selected from the group consisting of:

(i) [the] an expression vector [of Claim 8] comprising

(A) an isolated nucleic acid sequence of alternative splice variants selected from the group consisting of:

(a) the nucleic acid sequence depicted in any one of SEQ ID NO: 1 to SEQ ID NO: 26;

(b) nucleic acid sequences having at least 90% identity with the sequence of (a) with the proviso that each sequence is different than the original nucleic acid sequence from which the sequences of (a) have been varied by alternative splicing;  
and

(c) fragments of (a) or (b) of at least 20 b.p., provided that said fragment contains a sequence which is not present, as a continuous stretch of nucleotides, in the original nucleic

acid sequence from which the sequences of (a) have been varied  
by alternative splicing; and

(B) control elements for the expression of the nucleic acid  
sequence in a suitable host; and

(ii) any one of the amino acid sequences of Claim 4.